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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,442	03/07/2000	Gopinathan K. Menon	680.0035USU	1007
<div>7590 08/28/2007 Charles NJ Ruggiero Esq Ohlandt Greeley Ruggiero & Perle One Landmark Square 9th Floor Stamford, CT 06901-2682</div>			<div>EXAMINER BARHAM, BETHANY P</div>	
			<div>ART UNIT 1615</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 08/28/2007</div>	<div>DELIVERY MODE PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/521,442	MENON, GOPINATHAN K.	
	Examiner	Art Unit	
	Bethany P. Barham	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/11/2007</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

Receipt of IDS filed on 06/11/07 is acknowledged. Receipt of Applicant's Remarks filed on 06/01/2007 is also acknowledged. Claims 36-51 are pending. Claims 36-51 are rejected.

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 06/01/2007 has been entered.

Response to Arguments and Remarks

Rejections-35 USC § 112:

Applicants have submitted substantial art and arguments, specifically US Patent # 6,852,343 B2, which not only teaches treating cellulite with an oil from a plant but also teaches that cellulite is connected to expression of PPAR, thereby rendering the 112 enablement rejection moot.

The Examiner would like to point out that 'ameliorating or treating cellulite' is being defined in this instance as the improvement of aesthetic appearance of cellulite.

Since the prior art seems to be in conflict as to whether or not cellulite can actually be treated. Applicant submitted 3 clinical studies (all post filing date art) with their last response, and even those studies such as Rao et al in 2005, teach that cellulite has limited treatment options that are tolerable and effective, that there remains a poor understanding of the pathophysiology coupled with very few scientifically based studies, and that the degree to which any remedy is effective in cellulite clearance or reduction remains questionable (Rao et al, Summary and Intro.). Rao et al discloses several methods for evaluating cellulite with the 'observation' or visual method being the best and most relied upon and that various predisposing factors are known to contribute to cellulite, however in their study the only one that they kept constant was gender (as all subjects were female), which throws significant deviation into any results obtained (pg. 96-97, predisposing factors and evaluation). As such they discuss that there is no current cure or gold standard for the treatment of cellulite due in part to the minimal understanding of cellulite pathophysiology and poor therapeutic effectiveness of most treatment modalities (pg. 100, Management). They also acknowledge the various inherent flaws in their study that can lead to considerable error and deviation, but then conclude that they demonstrate a topical agent can be used to treat cellulite (pg. 101, present study).

Further, Bertin et al as submitted by applicant states that the events leading to the appearance of cellulite are still debated and most of the results with the product and placebo were indistinguishable, except for the improvement of visual or aesthetic

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appearance and concluded that a measurable activity was observed for the active product (pg. 199, intro; pg. 205, results, and pg. 210, conclusion).

It is the Examiner's understanding from the art taught that there still seems to exist considerable debate as to the etiology of cellulite (also see cited as interest) and even post dated double-blind studies acknowledge this as well as the fact that treatment is not currently known.

CITED AS INTEREST

A review article "Cellulite: nature and aetiopathogenesis" by Terranova, F. et al (2006), which teaches that only a limited number of studies on cellulite have been published and that many have reached antithetical conclusions, that it is not yet possible to reconcile the extreme differences of opinion, and that three major and conflicting theories have emerged in relation to the ethiopathogenesis of cellulite (abstract). They also teach that numerous known methods and treatments for cellulite have only a fleeting moment of triumph before proving to be ineffective (pg. 158, Intro.). They conclude that since no studies have been published to prove or disprove theories of ethiopathogenesis of cellulite and no data available to clarify whether the recently identified functional properties of the adipose tissue are involved in pathogenesis and therefore there remains only theory and hypothesis (pg. 163, last paragraph).

Further, an Editorial "The Disease of Cellulite" by Zoe Diana Draelos (2005), teaches that the exact etiology of cellulite is unknown, but that several theories deserve

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mention (pg. 221, 3rd Paragraph). The author states that "trying to treat cellulite is much like trying to ignore the normal female physiology that allows for the continuation of the species" (pg. 222, last Paragraph).

NEW REJECTIONS

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/53176 ('176).

The limitations of claims 36-51 are taught:

- '176 teaches novel pharmaceutical, dietetic and cosmetic compositions based on tioctic acid and cysteine useful for the prevention and treatment of conditions cause by oxidative stresses and alterations of both aerobic and anerobic energetic metabolism by activation of mitochondrial energetic enzyme systems are described (abstract, claim 1 and 7). The compositions also contain essential fatty acids, such as the omega-3-ones, particularly linseed oil and perilla oil each one in amounts between 2-8% by weight (claim 4; and pg. 6, lines 14-20). These

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compositions are taught to be useful as prevention and/or treatment of membranopathies, lipsclerosis or cellulitis (claim 19; and pg. 3, lines 26-27). The compositions are taught to be topical, pharmaceutical and cosmetic formulations (creams, ointments, salves, etc) and of dietetic supplement (pg. 5, lines 16-20). Example 7 teaches a liposclerosis (cellulitis) treatment double blind study with a cream for topical application daily for a month.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add perilla oil to composition in Example 7 for the treatment of cellulitis especially since claim 4 teaches that perilla oil can be added in the amount of 2-8%, which is within the range claimed by applicant. One of ordinary skill in the art would recognize that applying a topical cream daily as taught in Example 7, includes at least once daily. As such '176 renders obvious the instant claims.

Correspondence

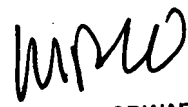
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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